**INDIUM IN-111 CHLORIDE - indium in-111 chloride solution**
Mallinckrodt Inc.

Rx Only.

Diagnostic - For use only in radiolabeling OncoScint® CR/OV (Satumomab Pendetide) and ProstaScint™ (Capromab Pendetide).

Radioimmunotherapy - For use only in radiolabeling Zevalin™ (Ibritumomab Tiuxetan).
FOR SINGLE USE ONLY

## DESCRIPTION

Indium In 111 Chloride Sterile Solution is indicated for radiolabeling OncoScint CR/OV and ProstaScint preparations used for in vivo diagnostic imaging procedures. It is also indicated for radiolabeling Zevalin™ preparations used for Radioimmunotherapy procedures. It is supplied as a sterile, non-pyrogenic solution of Indium In 111 Chloride in 0.05 molar hydrochloric acid. No carrier has been added to the solution. Each 0.5 milliliter of the solution contains 185 megabequerels (5 millicuries) of indium In 111 chloride at time of calibration (specific activity of >1.85 GBq/μg Indium; >50 mCi/μg Indium at this time of calibration). The solution pH is 1.1 to 1.4.

## RADIONUCLIDIC PURITY

Indium In 111 is cyclotron produced by the proton irradiation ((p, 2n) reaction) of cadmium Cd 112 enriched target. At time of calibration, it contains not less than 99.925% indium In 111 and, not more than 0.075% indium In 114m and zinc Zn 65 combined. At the time of expiration, it contains not less than 99.85% indium 111 and not more than 0.15% indium In 114m and zinc Zn 65 combined. No carrier has been added.

## RADIOCHEMICAL PURITY

At the time of calibration, the Indium In 111 Chloride Sterile Solution contains not less than 95% of the Indium present as ionic $In^{3+}$.

## CHEMICAL PURITY

Indium In 111 Chloride Sterile Solution is tested for the following metallic impurities; copper, iron, cadmium, lead, zinc, nickel, and mercury, and contains extremely low levels of these metals. The sum of the individual impurity ratios for the metals listed is not more than 0.60 ppm.

## PHYSICAL CHARACTERISTICS

Indium In 111 decays by electron capture to cadmium Cd 111 (stable) with a physical half-life of 67.32 hours (2.81 days)[1]. Photons useful for detection and imaging are listed in Table 1.

Table 1. Principal Radiation Emission Data[2]

| Radiation | Mean Percent Per Disintegration | Mean Energy (keV) |
|---|---|---|
| Gamma-2 | 90.2 | 171.3 |
| Gamma-3 | 94.0 | 245.4 |

[2]Kocher, David C., "Radioactive Decay Data Tables", DOE/TIC-11026, 115 (1981).

**1**From Radiopharmaceutical Internal Dosimetry Information Center, Oak Ridge Associated Universities, Oak Ridge, TN 37831-0117, February 1985.

## EXTERNAL RADIATION

The exposure rate constant for 37 MBq (1 mCi) of Indium In 111 is $8.3 \times 10^{-4}$ C/kg/hr (3.21 R/hr) at 1 cm. The specific gamma ray constant for Indium In 111 is 3.21 R/hr-mCi @ 1 cm[1]. The first half-value thickness of lead (Pb) is 0.023 cm. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in Table 2. For example, the use of 0.834 cm of Pb will decrease the external radiation exposure by a factor of about 1000.

Table 2. Indium In 111 Radiation Attenuation by Lead Shielding[1]

| Shield Thickness (Pb) cm | Coefficient of Attenuation |
|---|---|
| 0.023 | 0.5 |
| 0.203 | $10^{-1}$ |
| 0.513 | $10^{-2}$ |
| 0.834 | $10^{-3}$ |
| 1.12 | $10^{-4}$ |

These estimates of attenuation do not take into consideration the presence of longer-lived contaminants with higher energy photons, namely Indium In 114m.
To correct for physical decay of Indium In 111, the fractions that remain at selected intervals before and after calibration time are shown in Table 3.
Table 3. Indium In 111 Physical Decay Chart, Half-life 67.32 hours (2.81 days)

| Hours | Fraction Remaining | Hours | Fraction Remaining |
|---|---|---|---|
| -72 | 2.10 | 0* | 1.00 |
| -60 | 1.85 | 6 | 0.94 |
| -48 | 1.64 | 12 | 0.88 |
| -36 | 1.45 | 24 | 0.78 |
| -24 | 1.28 | 36 | 0.69 |
| -12 | 1.13 | 48 | 0.61 |
| -6 | 1.06 | 72 | 0.48 |

*Calibration time

**CLINICAL PHARMACOLOGY**
Please refer to the package insert for OncoScint CR/OV, ProstaScint or Zevalin for this information on the final drug product.

**INDICATIONS AND USAGE**
Indium In 111 Chloride Sterile Solution is indicated for radiolabeling OncoScint CR/OV or ProstaScmt preparations used for in vivo diagnostic imaging procedures. It is also indicated for radiolabeling Zevalin preparations used for Radioimmunotherapy procedures.
Please refer to the package insert for OncoScint CR/OV, ProstaScint or Zevalin for information on the final drug product.

**CONTRAINDICATIONS**
Please refer to the package insert for OncoScint CR/OV, ProstaScint, or Zevalin for this information on the final drug product.

**WARNINGS**
CONTENTS OF THE VIAL OF INDIUM In 111 CHLORIDE SOLUTION ARE INTENDED ONLY TO BE USED AS AN INGREDIENT FOR RADIOLABELING ONCOSCINT CR/OV OR PROSTASCINT FOR USE IN IN VIVO DIAGNOSTIC IMAGING PROCEDURES OR TO BE USED AS AN INGREDIENT FOR RADIOLABELING ZEVALIN™ FOR USE IN RADIOIMMUNOTHERAPY PROCEDURES, AND ARE NOT TO BE ADMINISTERED DIRECTLY TO HUMANS.

**PRECAUTIONS**

**General**
Caution must be used to maintain proper aseptic technique while withdrawing and transferring contents of the Indium Chloride solution vial.
Do not use after expiration time and date indicated on vial label.
Contents of the vial are radioactive and adequate shielding and handling precautions must be maintained at all times.

**Carcinogenesis, Mutagenesis and Impaired Fertility**
Please refer to the package insert for OncoScint CR/OV, ProstaScint, or Zevalin for this information on the final drug product.

**Pregnancy Category**
Please refer to the package insert for OncoScint CR/OV, ProstaScint, or Zevalin for this information on the final drug product.

**Nursing Mothers**
Please refer to the package insert for OncoScint CR/OV, ProstaScint, or Zevalin for this information on the final drug product.

**Pediatric Use**
Please refer to the package insert for OncoScint CR/OV, ProstaScint, or Zevalin for this information on the final drug product.

**ADVERSE REACTIONS**
Please refer to the package insert for OncoScint CR/OV, ProstaScint, or Zevalin for this information on the final drug product.

**DOSAGE AND ADMINISTRATION AND RADIATION DOSIMETRY**
Please refer to the package insert for OncoScint CR/OV, ProstaScint, or Zevalin for this information on the final drug product.

**HOW SUPPLIED**

Indium In 111 Chloride Sterile Solution is supplied in 10 mL vials containing 0.5 mL of solution. It is a sterile non-pyrogenic solution in 0.05 molar hydrochloric acid. No carrier is added to the solution. Each 0.5 mL contains 185 megabequerels (5 millicuries) of Indium In 111 Chloride at time of calibration. The pH of the solution is 1.1 to 1.4.

**SPECIAL STORAGE AND HANDLING**

The contents of the vial are radioactive and adequate shielding and handling precautions must be maintained. Store at controlled room temperature 20-25°C (68-77°F) [See USP].

Storage and disposal of Indium In 111 Chloride Sterile Solution should be controlled in a manner that is in compliance with the appropriate regulations of the government agency authorized to license the use of the radionuclide.

The vial should be kept inside its transportation shield whenever possible and should be handled with forceps when contents are being removed.



Revised 09/2002
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